In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-1881V

CHRISTINE HARBISON, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: June 10, 2024

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Alexa Roggenkamp, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLMENT[1]

On December 16, 2020, Christine Harbison filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges a Table injury - that she suffered a shoulder injury related to vaccine administration ("SIRVA") after receiving an influenza ("flu") vaccine on

[1] Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Ruling will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

November 6, 2018. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

After a full review of the evidence, I find that Petitioner has satisfied all Table requirements for a SIRVA Table injury, and is otherwise entitled to compensation for her injury.

I. Relevant Procedural History

After the case's initiation and SPU assignment, Respondent filed a Rule 4 Report recommending that entitlement to compensation be denied under the terms of the Vaccine Act. ECF No. 33. Specifically, Respondent argues that the evidence preponderates against a finding that the onset of Petitioner's shoulder pain occurred within 48 hours of her vaccination. *Id.* at 7-8. In reaction, on December 12, 2022, Petitioner filed a Motion for a Ruling on the Record (hereinafter "Motion"), pursuant to my Order. ECF No. 38. In her Motion, Petitioner argues that she has demonstrated onset within 48 hours of her flu vaccination, and otherwise satisfied all requirements under the Vaccine Act and established entitlement to compensation for a Table SIRVA injury. *Id.* No Reply brief was filed. This matter is ripe for my resolution.

II. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[3] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;

[3] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. Section 11(c)(1)(A)(B)(D)(E).

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (*e.g.* NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

III. Relevant Factual Evidence

I have fully reviewed the evidence, including all medical records and affidavits, and the parties' briefing. But I have limited my review below to the evidence most relevant to resolving the issue of onset:

A. Records

- Prior to her vaccination, Petitioner suffered some significant comorbidities, including lumbar radiculopathy, left wrist carpal tunnel syndrome, left hand neuropathy, fibromyalgia, and chronic pain among other ailments. *See* Ex. 1; Ex. 2 at 5-18.

- Petitioner received the flu vaccine in her left deltoid at her primary care provider's ("PCP") office at a visit dated November 5, 2018. Ex. 1 at 1. [4]

- A month later, on December 5, 2018, Petitioner was seen at her PCP office for "flu, nasal congestion, [and a] cough." Ex. 2 at 21. Petitioner was assessed with a "URI" or upper respiratory infection in addition to her pre-existing conditions, including neuropathy and fibromyalgia. Petitioner received Solu-Medrol and Rocephin injections in her gluteus maximus. *Id.*

- On January 17, 2019, Petitioner was seen again at her PCP office for a follow-up visit with complaints of left-hand pain Ex. 2 at 22. She was assessed again with URI, neuropathy, fibromyalgia among other conditions. *Id.*

[4] I observe that while the Petition, Petitioner's sworn statements, and at least one contemporaneous treatment record references a vaccination date of November 6, 2018, the vaccine administration records document that the flu vaccine was administered on November 5, 2018. Ex. 1; Ex. 2 at 24; Ex. 7; Ex. 8 at 20; Ex. 9; Ex. 10. However, I don't find that it is necessary to resolve the exact date of vaccination to find whether onset occurred within 48 hours of Petitioner's vaccination.

- On February 27, 2019, 114 days (or nearly four months) after her flu vaccination, Petitioner returned to her PCP with a complaint of "L[eft] arm pain since Nov[ember] from flu shot [on] 11/6/18." Ex. 2 at 24. The record provides Petitioner had reduced range of motion and complaints of left arm and shoulder pain. *Id.*

- Petitioner was seen again by her PCP on March 11, 2019. Ex. 2 at 27. Her PCP again documented reduced range of motion and assessed her with "? SIRVA." *Id.*

- Petitioner underwent an MRI on March 12, 2019, of her left shoulder. Ex. 6 at 109 -110. The "[I]ndication" stated "Patient got the flu shot in November and has been unable to lift her arm ever since. Suspected rotator cuff tear." *Id*. at 109. The MRI impression found: "Advanced supraspinatus and infraspinatus tendinitis without discrete tear. Intermediate grade partial-thickness tear to the subscapularis tendon insertion. Nonspecific glenohumeral joint effusion. Subacromial subdeltoid bursitis. Narrowing of the posterior subacromial space." *Id.* at 110.

- Petitioner was seen again by her PCP on April 11, 2019, in follow-up to her MRI. Ex. 2 at 30. Her PCP noted her findings of left shoulder bursitis and a subscapular tear, and again assessed her with "? SIRVA." *Id.*

- On April 29, 2019, Petitioner sought treatment from orthopedist Judith Penton, MD, for her left shoulder pain. Ex. 3 at 73. Dr. Penton's history provides that Petitioner's primary reason for the visit was "pain in the left shoulder which has been present for 6 months." *Id*. Dr. Penton further notes that Petitioner stated, "her pain began around the time she got a flu shot on the left side." *Id.* Dr. Penton's impression was "[l]eft shoulder adhesive capsulitis." *Id.* at 75. Dr. Penton administered two left shoulder steroid injections, prescribed an anti-inflammatory, and referred Petitioner to physical therapy." *Id.*

- Thereafter, Petitioner continued to treat for her shoulder injury, in addition to her other co-morbidities.

B. Declaration

Petitioner executed a signed and sworn declaration on December 5, 2022, addressing her November 2018 vaccination and subsequent shoulder injury. Ex. 9. Petitioner acknowledges that prior to her vaccination she suffered, and continues to suffer, from fibromyalgia. *Id.*, ¶ 3. However, she provides that she had no pre-vaccination pain in her left shoulder. *Id*. She states that beginning on her way home from the vaccination, her arm felt "stiff and weird." *Id.*, ¶ 5. She tried to ice, heat, and resting it for a few days. She told her daughter, husband, and cousin that her "arm is hurting since that

dang flu shot." Petitioner's cousin told her that same thing had happened to her and provided her "the website." *Id*.

Petitioner states she did not initially report her shoulder pain at her December and January PCP appointments because she suffers from fibromyalgia, and thus initially attributed her pain to that condition. *Id.,* ¶ 6. She states the areas of her pain on her body often change, and she therefore has "adopt[ed] a 'wait and see' philosophy – as a general rule, I wait about 3 months prior to seeking treatment for new pain and assume it is related to fibromyalgia. Then, if my pain won't go away, I will seek treatment for it." *Id*.

Petitioner's husband, Gary Harbison, also executed a sworn statement in regard to Petitioner's vaccination and onset of shoulder pain. Ex. 10. Mr. Harbison states that Petitioner received the vaccination on November 6, 2018 and he drove her "home that day." *Id.,* ¶¶ 2-3. He recalls that Petitioner "mentioned that her left shoulder was sore" that "afternoon/evening." *Id.,* ¶ 4. He notes that "about 1-2 days later, [she] could not raise her arm above her head. I recall worrying that she may have injured her rotator cuff since I had a shoulder injury from a fall with similar symptoms." *Id.,* ¶ 5. Mr. Harbison also states that he "did not insist that [Petitioner] seek treatment for her left shoulder as she has always been one to push through the pain." *Id.,* ¶ 6.

IV. Findings of Fact

A. Onset

The primary disputed factor in this case is whether Petitioner's first post-vaccination symptom or manifestation of onset (specifically pain) of her shoulder injury occurred within 48 hours of her flu vaccination as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(a)(XIV)(B) (seasonal influenza vaccines); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI); ECF No. 33 at 7-8. Based upon a review of the entire record, and for the reasons set forth below, I find that it more likely than not did.

In this case, as correctly pointed out by Respondent, the records corresponding to Petitioner's first two appointments with medical providers following her November 2018 vaccination contain no reference to shoulder pain at all. Rather, these encounters consist of a PCP visit for the flu, congestion, and a cough on December 5, 2018, and a subsequent PCP encounter for a complaint of hand pain. Respondent argues that since Petitioner reported another type of upper extremity pain at her January 17, 2019 visit, it is unlikely her PCP would have failed to record any report of shoulder pain. ECF No. 33 at 8.

Petitioner, however, does not contend that she reported her shoulder pain at these earlier appointments (and thus that those initial records mistakenly omit information). Rather, she explains in her sworn statement that her preexisting fibromyalgia caused her to assume that new pain sensations were likely explained by it – and accordingly that she generally hesitated to obtain treatment for new pain sensations unless they persisted for weeks or months. Ex. 9. Additionally, Petitioner and her husband both recall in their sworn statements that she experienced shoulder pain the day she received her vaccination. Ex. 9; Ex. 10.

It is not unusual in my experience adjudicating SIRVA claims that petitioners delay treatment, hoping their shoulder pain and/or soreness will abate. Here, Petitioner's fibromyalgia is an added consideration that explains her reluctance to report the pain. More significantly, Petitioner's statement is corroborated by contemporaneous medical records, if not the most contemporaneous medical records, which document that Petitioner sought treatment for her shoulder pain nearly four months after her vaccination. Petitioner reported to her PCP on February 27, 2019, that she had specifically experienced "L[eft] arm pain since Nov[ember] from flu shot 11/6/18." Ex. 2 at 24. This statement is consistent with her subsequent reports to her providers regarding the onset of her shoulder pain. Ex. 6 at 109 (Petitioner's March 12, 2019 MRI indication providing "Patient got the flu shot in November and has been unable to lift her arm ever since. Suspected rotator cuff tear."); Ex. 3 at 73 (April 11, 2019 orthopedist evaluation pain began "around the time she got a flu shot injection.").

The fact that *some* of these references to onset are not precise in terms of time or date does not prevent a favorable finding. As I have previously observed, "the Vaccine Act clearly does *not* require that symptoms be recorded within a specific timeframe to be preponderantly established. Rather, it requires only that onset *occurs* in the relevant timeframe." *Niemi v. Sec'y of Health & Hum. Servs.,* No. 19-1535V, 2021 WL 4146940, at *4 (Fed. Cl. Aug. 10, 2021) (citing Section 13) (emphasis in original). Neither does the Act require that the medical records document an exact date that the onset of a petitioner's shoulder pain began. A special master may thus find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2).

Based on the record as a whole, I find that Petitioner has established the onset of her injury likely occurred within 48 hours of her vaccination. Of course, Petitioner's delay in seeking medical treatment demonstrates that she was able to tolerate the pain initially,

and is indicative of a somewhat less severe SIRVA – a factor I will consider in awarding damages for pain and suffering in this case.

B. Other Table Requirements and Entitlement

Based upon the above, and my review of the record, Petitioner has established all other requirements for a Table SIRVA claim. 42 C.F.R. § 100.3(c)(10).[5] However, even if a petitioner has satisfied the requirements of a Table injury or established causation-in-fact, he or she must also provide preponderant evidence of the additional requirements of Section 11(c), *i.e.*, receipt of a covered vaccine, residual effects of injury lasting six months, *etc*. *See generally* Section 11(c)(1)(A)(B)(D)(E). But those elements are established or undisputed in this claim. I therefore find that Petitioner is entitled to compensation in this case.

Conclusion

Based on the entire record, I find that Petitioner has provided preponderant evidence satisfying all requirements for a Table SIRVA. Petitioner is entitled to compensation. A Damages Order will issue.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[5] Respondent also remarks (in a footnote of his Rule 4 Report addressing onset) that "[P]etitioner's multiple comorbidities – including osteoarthritis of the left shoulder make it difficult to distinguish whether and to what extent [P]etitioner's symptoms were attributable to any alleged vaccine injury." ECF No. 33 at 8, n. 3. However, Respondent does not further develop this argument, or dispute that Petitioner has failed to establish any SIRVA Table requirement raise aside from onset. While I have found that Petitioner has established a Table SIRVA claim, I acknowledge her co-morbidities certainly explain some of her overall severity, and will reasonably impact any damages award. Moreover, based on my preliminary review, Petitioner's shoulder treatment subsequent to July 2019, appears related to her osteoarthritis, rather than in treatment of the SIRVA. Ex. 3 at 87-88 (Dr. Penton on July 29, 2019, recommended Petitioner consult with Dr. Matthew Williams "to discuss the role of primary shoulder replacement in the face of her significant osteoarthritis" after a July 2019 MRI showed significant osteoarthritis); Ex. 3 at 93 (Dr. Williams observed at an August 15, 2019 appointment that Petitioner states she was "diagnosed with frozen shoulder in the past after a flu shot, which has been resolved.").

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